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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Class II Special Controls for Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0437. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Reporting--21 CFR part 803

OMB Control Number 0910-0437--Revision

In the *Federal Register* of February 21, 2020 (85 FR 10110), we published a proposed order to reclassify certain human immunodeficiency virus (HIV) serological diagnostic and supplemental tests and HIV nucleic acid (NAT) diagnostic and supplemental tests from class III (premarket approval) into class II (special controls) (the proposed order). In the proposed order, FDA proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness for these devices. The proposed special controls would require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional premarket notification (510(k)) submission for a device within the scope of the proposed order.

Currently, manufacturers of HIV serological diagnostic and supplemental tests and HIV NAT diagnostic and supplemental tests are subject to FDA regulations in part 820 (21 CFR part 820), which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. Manufacturers are required to maintain complaint files and to review and evaluate complaints for these devices under § 820.198 (21 CFR 820.198) (approved under OMB control number 0910-0073).

Complaints required to be reported in the annual logs under the proposed special controls, such as certain complaints involving unusually high invalid rates or issues with users conducting the test, may not meet the definition of a medical device report required to be reported to FDA under 21 CFR part 803 (Medical Device Reporting; currently approved under OMB control number 0910-0437), but could potentially affect the safety and effectiveness of these devices. The submission of the complaint log would provide us with earlier notification of concerns and

enable us to determine whether they have been adequately addressed. The Agency usually would not evaluate this kind of complaint information until an FDA inspection, which typically occurs less frequently than annually. We believe implementing these specific reporting measures as part of the special controls would be necessary to provide a reasonable assurance of safety and effectiveness for HIV diagnostic and supplemental tests subject to the proposed order.

Finalizing the proposed order would add classification regulations for these devices in 21 CFR part 866 (Immunology and Microbiology Devices) at 21 CFR 866.3956 for the HIV serological diagnostic and supplemental tests, and 21 CFR 866.3957 for the HIV NAT diagnostic and supplemental tests, and establish special controls necessary to provide reasonable assurance of their safety and effectiveness. As described above, the special controls would require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional 510(k) submission for one of these devices. We are requesting approval to revise the scope of the information collections included in OMB control number 0910-0437 (medical device reporting) to include the information collection associated with this special control provision.

Description of Respondents: The respondents to the information collection are manufacturers of HIV diagnostic and supplemental test devices that would be subject to the proposed order, if finalized.

In the *Federal Register* of June 25, 2021 (86 FR 33708), we published a 60-day notice requesting public comment on the new reporting provisions of the proposed order. One comment was received, however it was not responsive to the four information collection topics solicited, nor did it suggest FDA revise its burden estimate.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Proposed 21 CFR 866.3956(b)(1)(iii) and 866.3957(b)(1)(iii), Submission of log to FDA	10	1	10	3	30

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of the average burden per response on our experience with other types of annual report submissions. We base our estimate of the number of affected respondents on the expected number of manufacturers that would be submitting a 510(k) for a new device or changes to an existing device that would require a 510(k).

As noted above, manufacturers of the devices subject to the proposed order must already maintain complaint files and review and evaluate complaints under § 820.198. If the proposed order is finalized as proposed, we estimate it would take a manufacturer approximately 3 hours annually to review their existing records, prepare the complaint log, and submit it to FDA. Although respondents may submit the information electronically through the FDA Electronic Submission Gateway, on paper, or electronic media (e.g., CD, DVD) to the Center for Biologics Evaluation and Research's Document Control Center, we assume that all manufacturers will submit their logs electronically.

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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